



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,718	06/08/1998	HAKAN NYQVIST	1103326-0503	6402

22466 7590 03/11/2003

ASTRA ZENECA PHARMACEUTICALS LP  
GLOBAL INTELLECTUAL PROPERTY  
1800 CONCORD PIKE  
WILMINGTON, DE 19850-5437

EXAMINER

SOLOLA, TAOFIQ A

ART UNIT	PAPER NUMBER
----------	--------------

1626

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/077,718

Applicant(s)

NYQVIST ET AL.

Examiner

Taofiq A. Solola

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 3-5, 12-18 and 20-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 3-5, 12-18, 20-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Claims 3-5, 12-18, 20-33 are pending in this application.

Claims 1-2, 6-11, 19, are canceled.

***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/7/03 has been entered.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5, 12-18, 20-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Evenden et al., WO 95/11891.

Evenden et al., disclose (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide salts (e.g. tartaric salts), their composition and method of use for the treatment of CNS disorders. See page 6, lines 20, and line 37 pages 6 to page 7, line 7. The Examiner assumes the salt of Evenden et al., is physically stable, is soluble and "has good dissolution properties" absent a showing to the contrary.

Evenden et al., also disclose a process of making the salts comprising adding ether solution of the compounds to a second ether solution of hydrochloric acid.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-5, 12-15 and 20-21, 23-30, are rejected under 35 U.S.C. 103(a) as being unpatentable over Evenden et al., WO 95/11891.

Applicants claim tartaric salts of (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide, their composition and method of use for the treatment of CNS disorders. In preferred embodiment the salt is characterized as stable, soluble and having "good dissolution properties."

**Determination of the scope and content of the prior art (MPEP §2141.01)**

Evenden et al., teach similar compounds having general formula I (page 5, lines 1-20); their organic and inorganic acids salts, (page 6, line 37 to page 7, line 17) their pharmaceutical preparations (compositions) and method of use for the treatment of CNS disorders. See the abstract, page 11, lines 1-11. Evenden et al., teach tartaric acid salt as illustrative (example) of the salt. See page 7, lines 4-6, and that the salt can be "readily prepared by methods known in the art."

**Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)**

The difference between the instant invention and that of Evenden et al., is that the tartaric salt is prepared in the instant while Evenden et al., do not prepare it. Also, the salt is characterized in the instant as stable, soluble and having "good dissolution properties" while Evenden et al., do not characterize it.

*Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)*

Making a known compound or salt and further characterizing such do not make the compound or salt inventive or patentable. Therefore, the instantly claimed invention is prima facie obvious from the teaching of Evenden et al. One of ordinary skill in the art would have known to make the salt at the time this invention was made. The motivation to make the claimed salt is from the teaching of Evenden et al., that tartaric salt is an illustrative example and that it could be "readily prepared by methods known in the art."

Claims 16-18, 22, and 31-33, are rejected under 35 U.S.C. 103(a) as being unpatentable over Evenden et al., WO 95/11891.

Applicants claim a process of making tartaric salts of (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide comprising dissolving (R)-3-N,N-dicyclobutylamino-8-fluoro-3,4-dihydro-2H-1-benzopyran-5-carboxamide in an aqueous or non-aqueous organic solution of tartaric acid.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Evenden et al., teach similar compounds having general formula I (page 5, lines 1-20), and a process of making their salts comprising adding ether solution of the compounds to a second ether solution of hydrochloric acid. Evenden et al., also teach that tartaric acid could be used to make the salts (page 7, line 7).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant invention and that of Evenden et al., is that the tartaric salt is prepared in the instant while Evenden et al., do not prepare it.

Finding of prima facie obviousness---rational and motivation (MPEP §2142.2413)

However, Evenden et al., teach that the salts (including tartaric) could be "readily prepared by methods known in the art." For example, the process of Evenden et al., is a known method at the time of the instant invention. Therefore, the instant process is prima facie obvious from the teaching of Evenden et al. One of ordinary skill in the art would have known to prepare the salt using the process of Evenden et al., at the time the invention was made. The motivation for using the process of Evenden et al., is because Evenden et al., teach that the salt could be "readily prepared by methods known in the art."

Applicant's arguments filed 1/7/03 have been fully considered but they are not persuasive. Applicant contends that the prior art of Evenden et al., fails to provide a suggestion or motivation to make the tartaric salt, and that the instant salt shows unexpected result of stability and solubility. This is not persuasive for reason set forth above. Applicant further argues that the Office regularly allow compounds directed to new forms of old compounds. This is not persuasive because each application is examined on its merit.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690. The examiner is on flexible work schedule and is generally out of the office on Wednesdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



**TAOFIQ SOLOLA  
PRIMARY EXAMINER**

Group 1626

March 6, 2003